

§ 1635.3

Physician, the Office of Compliance, and the Office of Technology Assessment.

(f) *Employment agency* is defined in 42 U.S.C. 2000e(c) to mean any person regularly undertaking with or without compensation to procure employees for an employer or to procure for employees opportunities to work for an employer and includes an agent of such a person.

(g) *Joint labor-management committee* is defined as an entity that controls apprenticeship or other training or retraining programs, including on-the-job training programs.

(h) *Labor organization* is defined at 42 U.S.C. 2000e(d) to mean an organization with fifteen or more members engaged in an industry affecting commerce, and any agent of such an organization in which employees participate and which exists for the purpose, in whole or in part, of dealing with employers concerning grievances, labor disputes, wages, rates of pay, hours, or other terms or conditions of employment.

(i) *Member* includes, with respect to a labor organization, an applicant for membership.

(j) *Person* is defined at 42 U.S.C. 2000e(a) to mean one or more individuals, governments, governmental agencies, political subdivisions, labor unions, partnerships, associations, corporations, legal representatives, mutual companies, joint-stock companies, trusts, unincorporated organizations, trustees, trustees in cases under title 11, or receivers.

(k) *State* is defined at 42 U.S.C. 2000e(i) and includes a State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, and Outer Continental Shelf lands defined in the Outer Continental Shelf Lands Act (43 U.S.C. 1331 *et seq.*).

§ 1635.3 Definitions specific to GINA.

(a) *Family member* means with respect to any individual:

(1) A person who is a dependent of that individual as the result of marriage, birth, adoption, or placement for adoption; or

(2) A first-degree, second-degree, third-degree, or fourth-degree relative

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of the individual, or of a dependent of the individual as defined in § 1635.3(a)(1).

(i) First-degree relatives include an individual's parents, siblings, and children.

(ii) Second-degree relatives include an individual's grandparents, grandchildren, uncles, aunts, nephews, nieces, and half-siblings.

(iii) Third-degree relatives include an individual's great-grandparents, great grandchildren, great uncles/aunts, and first cousins.

(iv) Fourth-degree relatives include an individual's great-great-grandparents, great-great-grandchildren, and first cousins once-removed (i.e., the children of the individual's first cousins).

(b) *Family medical history*. Family medical history means information about the manifestation of disease or disorder in family members of the individual.

(c) *Genetic information*. (1) Genetic information means information about:

(i) An individual's genetic tests;

(ii) The genetic tests of that individual's family members;

(iii) The manifestation of disease or disorder in family members of the individual (family medical history);

(iv) An individual's request for, or receipt of, genetic services, or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or

(v) The genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology.

(2) Genetic information does not include information about the sex or age of the individual, the sex or age of family members, or information about the race or ethnicity of the individual or family members that is not derived from a genetic test.

(d) *Genetic monitoring* means the periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, caused by the

toxic substances they use or are exposed to in performing their jobs, in order to identify, evaluate, and respond to the effects of, or to control adverse environmental exposures in the workplace.

(e) *Genetic services.* Genetic services means a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education.

(f) *Genetic test*—(1) *In general.* “Genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.

(2) Genetic tests include, but are not limited to:

(i) A test to determine whether someone has the BRCA1 or BRCA2 variant evidencing a predisposition to breast cancer, a test to determine whether someone has a genetic variant associated with hereditary nonpolyposis colon cancer, and a test for a genetic variant for Huntington’s Disease;

(ii) Carrier screening for adults using genetic analysis to determine the risk of conditions such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome in future offspring;

(iii) Amniocentesis and other evaluations used to determine the presence of genetic abnormalities in a fetus during pregnancy;

(iv) Newborn screening analysis that uses DNA, RNA, protein, or metabolite analysis to detect or indicate genotypes, mutations, or chromosomal changes, such as a test for PKU performed so that treatment can begin before a disease manifests;

(v) Preimplantation genetic diagnosis performed on embryos created using invitro fertilization;

(vi) Pharmacogenetic tests that detect genotypes, mutations, or chromosomal changes that indicate how an individual will react to a drug or a particular dosage of a drug;

(vii) DNA testing to detect genetic markers that are associated with information about ancestry; and

(viii) DNA testing that reveals family relationships, such as paternity.

(3) The following are examples of tests or procedures that are not genetic tests:

(i) An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes;

(ii) A medical examination that tests for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins, or metabolites;

(iii) A test for infectious and communicable diseases that may be transmitted through food handling;

(iv) Complete blood counts, cholesterol tests, and liver-function tests.

(4) *Alcohol and Drug Testing*—

(i) A test for the presence of alcohol or illegal drugs is not a genetic test.

(ii) A test to determine whether an individual has a genetic predisposition for alcoholism or drug use is a genetic test.

(g) *Manifestation or manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this part, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.

§ 1635.4 Prohibited practices—in general.

(a) It is unlawful for an employer to discriminate against an individual on the basis of the genetic information of the individual in regard to hiring, discharge, compensation, terms, conditions, or privileges of employment.

(b) It is unlawful for an employment agency to fail or refuse to refer any individual for employment or otherwise discriminate against any individual because of genetic information of the individual.

(c) It is unlawful for a labor organization to exclude or to expel from the membership of the organization, or otherwise to discriminate against, any member because of genetic information with respect to the member.

(d) It is an unlawful employment practice for any employer, labor organization, or joint labor-management